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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,568

10/14/2009

Michael Tesar

047744-0125

8662

22428 7590 12/13/2011  
FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

12/13/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,568	<b>Applicant(s)</b> TESAR ET AL.	
	<b>Examiner</b> ANNE GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 85-89,91-96,98-105,107,108 and 142-148 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 100-105,107,108 and 142-148 is/are allowed.
- 7) ☒ Claim(s) 85,91-93,98 and 99 is/are rejected.
- 8) ☒ Claim(s) 86-89 and 94-96 is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/11</u> .                                                | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. Claims 85-89, 93-96, and 100-105 have been amended.  
Claims 1-84, 90, 97, 106, and 109-114 have been cancelled.  
Claims 142-148 have been added.
2. Claims 85-89, 91-96, 98-105, 107, 108, and 142-148 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on October 18, 2011 was filed after the mailing date of the non-final office action on July 18, 2011. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

### ***Objections Withdrawn***

5. The objection to the specification is withdrawn in view of applicant's amendment to the specification.
6. The objection to claims 140 and 141 is withdrawn in view of applicant's cancellation of the claims.

***Rejections Withdrawn***

7. The rejection of claims 126 and 127 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's cancellation of the claims.
8. The rejection of claims 85-89, 91, 92, and 117 under 35 U.S.C. 112, first paragraph as requiring a deposit of biological materials is withdrawn in view of applicant's arguments regarding the availability of the cell lines.
9. The rejection of claims 85-89, 91-96, 98-105, 107-113, 115-117, 126, 127, 140, and 141 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendment to the claims.
10. The rejection of claims 126 and 127 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's cancellation of the claims.
11. The rejection of claims 126, 127, 140, and 141 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's cancellation of the claims.
12. The rejection of claims 100, 101, 107, 108, and 117 under 35 U.S.C. 102(a, e) as being anticipated by Logtenberg, et al. (US PG PUB 2003/0211553, published September 5, 2008) is withdrawn in view of applicant's amendment to the claims.

***NEW GROUNDS of Rejection***

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 85, 91-93, 98, and 99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 97-130, 132, and 133 of copending Application No. 12/089806 (herein after '806), as evidenced by the '806 specification. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to antibodies that bind to CD30 and comprise the same functional properties. Since the claims in the '806 case have been deemed allowable, this is a true rejection, **NOT** a provisional rejection.

The instant claims recite an isolated human antibody that specifically binds an epitope of CD38 (SEQ ID NO: 22), wherein said antibody mediates killing of a CD38+ target cell by antibody dependent cellular cytotoxicity with at least five-fold better efficacy than chimeric OKT10 antibody (SEQ ID NOS: 23 and 24) under the same or substantially the same conditions when a human PBMC cell is employed as the effector cell, wherein said CD38+ target cell is selected from the group consisting of LP-1 (DSMZ: ACC41) and RPMI-8226 (ATCC: CCL-155), and wherein the ratio of effector cells to target cells is between about 30:1 and about 50:1, which is an IgG, which is an IgG1. An isolated human antibody that specifically binds to an epitope of CD38 (SEQ ID NO: 22), wherein said antibody mediates killing of a

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CD38-transfected CHO cell by cell dependent cytotoxicity with at least two-fold better efficacy than chimeric OKT10 antibody (SEQ ID NOS: 23 and 24) under the same or substantially the same conditions, which is an IgG, which is an IgG1.

The '806 claims recite an isolated antibody or antigen-binding fragment thereof that binds to CD38, which comprises the three variable heavy chain complementarity determining regions (H-CDRs) and the three variable light-chain complementarity determining regions (L-CDRs) that are in the variable heavy chain and variable light chain pairs selected from: (i) SEQ ID NO: 18 and 48, (ii) SEQ ID NO: 20 and 50, (iii) SEQ ID NO: 21 and 51, (iv) SEQ ID NO: 22 and 52, and (v) SEQ ID NO: 25 and 55, which is an IgG, which is an IgG1.

The '806 specification teaches the functional limitations found in the instant claims, specifically that the antibodies mediate killing of a CD38+ target cell by antibody dependent cellular cytotoxicity with at least five-fold better efficacy than chimeric OKT10 antibody under the same or substantially the same conditions when a human PBMC cell is employed as the effector cell, wherein said CD38+ target cell is selected from the group consisting of LP-1 (DSMZ: ACC41) and RPMI-8226 (ATCC: CCL-155), and wherein the ratio of effector cells to target cells is between about 30:1 and about 50:1 (see tables 1 and 2).

Since both sets of claims are drawn to an antibody that binds to CD38 with the same functional properties (i.e. mediating killing of a CD38+ target cell by antibody dependent cellular cytotoxicity with at least five-fold better efficacy than chimeric OKT10 antibody), the instant claims are anticipated by the '806 claims.

***Conclusion***

15. Claims 100-105, 107, 108, and 142-148 appear to be in condition for allowance.

Claims 85, 91-93, 98, and 99 are rejected.

Claims 86-89 and 94-96 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
December 8, 2011

/Anne M. Gussow/  
Primary Examiner, Art Unit 1643